UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

ELLEN MEHLMAN,	)	
	)	
Plaintiff,	)	Civil No. 06-199-P-H (DBH)
v.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

PLAINTIFF'S OPPOSITION TO ELI LILLY AND COMPANY'S MOTION TO EXCLUDE THE TESTIMONY OF JOHN J. HEFFERREN

COMES NOW Plaintiff Ellen Mehlman, through counsel, and opposes the Motion of Defendant Eli Lilly and Company ("Defendant" or "Lilly") to Exclude the Testimony of John J. Hefferren, and as grounds therefore states:

I. INTRODUCTION

The strongest evidence that the Lilly pill was the culprit in this case – the only pill that matches Plaintiff's mother's description – is Lilly's failure to confront Dr. Hefferren at his deposition, or to provide this court, with evidence of a cross-scored, flat DES pill that wasn't Lilly's. Defendant failed to do so because Defendant cannot. None exists.

In the early 1970's, when the DES disaster first made news, the drug industry came before congressional hearings on how its untested drug could have been given to millions of pregnant women. In order to shift the blame from itself and the liability of lawsuits such as this one, Lilly, the largest DES manufacturer, began to argue, as it does now, that it was not predominant in the DES market. Even though Lilly was the "Heinz ketchup" of the DES world and the predominant brand in Massachusetts, see Report of Harold Sparr, attached as Appendix 1, Lilly sought refuge in blaming the other, far less prominent, companies on the market.

Dr. Hefferren was introduced into DES litigation by Lilly and set forth in multiple cases as the leading expert on the shape of pills throughout the time DES was available. See, e.g., Selections from Lilly's Motions for Summary Judgment in Cutone v. Eli Lilly and Co., Civil Action No. 04-CV-12725 (D. Mass. 2006), Delaney v. Eli Lilly and Co., Civil Action No. 05-CV-10241 (D. Mass. 2006), Tait v. Eli Lilly and Co., C.A. No. 05-cv-2082 (S.D. Tex. 2006), Exhibits A-C of Appendix 2. Only when Dr. Hefferren's expertise was then used against Defendant and testified that the only flat-topped, round, cross-scored DES pill was Lilly's 25mg pill, see Deposition of John J. Hefferren, Ph.D. ("Hefferren Deposition"), pg. 177, App. 3, did Lilly denigrate his expertise and experience in identifying pharmaceuticals.

In fact, Lilly cannot provide this Court with a pill or a photograph of another DES pill that matches the Lilly product. That is why a hearing on this motion is critical – so Plaintiff can demonstrate to the Court the uniqueness of Lilly's pill. There is no question that Dr. Hefferren holds the zenith position in examining pills and determining what are common or uncommon shapes. The Court should have the opportunity to hear Dr. Hefferren and observe first hand what he is talking about. Dr. Hefferren is a combined fact and expert witness whose testimony comes from both his cataloguing of thousands of pills and his decades of experience in pharmaceutical formulation. If Dr. Hefferren is reliable enough for the American Medical Association and the Food and Drug Administration, he should be reliable enough for this Court.

II. DR. HEFFERREN'S TESTIMONY AS TO THE TECHNICAL DIFFICULTY OF A CROSS-SCORED PILL IS ADMISSIBLE

Defendant's allegation that Dr. Hefferren is not qualified in pill formulation is spurious. "The notion that Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993), requires particular credentials for an expert witness is radically unsound." Tuf Racing Prods., Inc. v. American Suzuki Motor Corp., 223 F.3d 585 (7th Cir.

2000). This Circuit's standard for experts does not require "that experts be blue-ribbon practitioners with optional certifications." United States v. Mahone, 453 F.3d 68, 71 (1st Cir. 2006).

Dr. Hefferren's qualifications as an expert in drug delivery systems has been relied upon by the American Society of Pharmacists, the Veterans Administration, and the Food and Drug Administration. See Curriculum Vitae of Dr. Hefferren, pgs. 2, 3, Exhibit 8-A to Def's Mtn., Docket No. 16-5. His education was in the kinetics of drug delivery. See Hefferren Deposition, pg. 11, App. 3. His current work is developing drugs for dental care. See id. pg. 12. In Dr. Hefferren's deposition, discussion his work included references to "drug delivery technology," a category that includes the formulation of pills, see id. pg. 37, and the difficulties of formulating a distinctively-shaped pill with a certain percentage of active ingredients, see id. pg. 185. Dr. Hefferren also testified at deposition that he was a reviewer of monographs for *National Formulary* and the *International Pharmacopoeia*. See id., pgs. 62-64. The monographs for both publications include the method of manufacturing a drug and the quality tests to insure its reliability. See "USP–NF—An Overview" *available at* http://www.usp.org/USPNF/ (last visited Sept. 27, 2007) (*National Formulary)*; "The International Pharmacopoeia (Ph.Int.) - general information," *available at* http://www.who.int/medicines/publications/pharmacopoeia/overview /en/index.html (last visited Sept. 27, 2007) (*International Pharmacopoiea*). Dr. Hefferren testified that he has personally participated in formulating "solid dosage forms" such as pills after receiving his degree. See Hefferren Deposition, pg. 151, App. 3.

As Dr. Hefferren testified, a cross-scored pill is a technically sophisticated dosage form. See Hefferren Deposition, pgs. 239-40. Defendant claims that this testimony is not relevant because Dr. Hefferren cannot exclude hypothetical other manufacturers of DES.[1] However, "[n]either Rule 702 nor Daubert require that an expert's testimony prove an element of the offering party's case for it to be admissible." Cook v. Rockwell Int'l Corp., No. 90-cv-00181-JLK, 2006 U.S. Dist. LEXIS 89121 at *19 (D. Colo. Dec. 7, 2006). An expert's testimony "need only be relevant to *an* issue in the case; it need not relate directly to the ultimate issue." See Smith v. Ford Motor Co., 215 F.3d 713, 721 (7th Cir. 2000) (allowing an expert to testify as to improvements that could have been made to a gearbox even though he could not opine as to whether the gearbox was defective through a design or manufacturing defect). Dr. Hefferren's testimony will reduce the number of unknown alternative DES manufacturers used by Lilly as an alibi and will support Plaintiff's allegation that it is unlikely that there is some hypothetical duplicate pill out there.

Defendant's contrary allegations – that "anyone" could have purchased the die-stamping equipment, while theoretically possible, cannot go to the admissibility of Dr. Hefferren. "Daubert does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. As long as an expert's testimony rests upon 'good grounds, based on what is known,' [citation omitted] it should be tested by the adversary process -- competing expert testimony and active cross-examination -- rather than excluded from jurors' scrutiny." See Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998). Dr. Hefferren's opinions on pill formulation are well-grounded in his years of education and experience.

Defendant's attempt to point out the existence of other cross-scored, non-DES pills ignores the difference between concave and flat-topped pills and assumes that the technical

[1] Defendant's contention that Plaintiff must show that Lilly's pill was unique, Def's Mtn. at 1, is neither the law nor at issue in this Motion. As Defendant did not move for summary judgment on that ground, it is not before the court at this time to decide what Plaintiff's burden of evidence is.

sophistication of both pills are the same, which has not been demonstrated. Dr. Hefferren was not asked about the particulars of any other companies named in Defendant's motion at deposition and Defendant has not established that Premo, Pitman-Moore, and Bryant are representative of pharmaceutical companies as a whole or made a flat, small, white cross-scored DES product, and those three companies did not manufacture such a DES product. If Defendant believes that the capability of other manufacturers is damning to Dr. Hefferren's testimony – a capability that defendant has not shown to be anything more than the hypothetical and unsupported allegations of counsel – the appropriate place to ask these questions is on cross-examination, not a Daubert challenge.

III. DR. HEFFERREN'S TESTIMONY ABOUT HIS PILL IDENTIFICATION RESEARCH IS ADMISSIBLE

Dr. Hefferren may also testify about the likelihood of there being another pill that looks like Lilly's from his investigations of pill shapes, both independently and as an expert for Plaintiff.[2] Dr. Hefferren has, admittedly, not looked at every pill in existence during 1964 and 1965. He has, however, examined hundreds of pills available during that time period and conducted a further survey of pill photographs for this litigation. From those experiences, Dr. Hefferren can inform the jury about the general trends in pill shape during the 1960's and that Lilly's 25mg DES pill was unique among those shapes.

"[T]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in

[2] Defendant cannot, as it attempts in its motion, require that Dr. Hefferren's individual sources of knowledge be considered separate from the conclusion that the combination of those sources leads to. Dr. Hefferren is called to give two kinds of testimony: testimony about the difficulty of formulating a pill that looks like Lilly's DES pill, and that Lilly's DES pill was an uncommon shape among pills generally. Whether an expert has a sufficient basis for his testimony is a quantitative, rather than a qualitative, standard; the court determines only whether the expert considered enough information to make the opinion reliable, not the quality of that information. See Cook v. Rockwell Int'l Corp., No. 90-cv-00181-JLK, 2006 U.S. Dist. LEXIS 89121 at *24 (D. Colo. Dec. 7, 2006). Therefore, the Court should look at the bases for Dr. Hefferren's testimony as to whether the combination of sources, even if incomplete of themselves, are sufficient for Dr. Hefferren to form an opinion.

cross-examination." Brown v. Wal-Mart Stores, Inc., 402 F. Supp. 2d 303, 308 (D. Me. 2005) (citing Larson v. Kempker, 414 F.3d 936, 941 (8th Cir. 2005)). Cf. International Adhesive Coating Co. v. Bolton Emerson Int'l, Inc., 851 F.2d 540, 545 (1st Cir. 1988) ("When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony – a question to be resolved by the jury.").

It is not critical for Dr. Hefferren to have looked at every pill on the market to formulate his opinion. In this District, a doctor has been allowed to testify that a cheeseburger caused a plaintiff's illness without ever testing the cheeseburger or testing the patient for the presumed foodborne illness. See Roney v. Wendy's Old Fashioned Hamburgers of N.Y., Inc., No. 2:05-cv-109-GZS, 2006 U.S. Dist. LEXIS 11303 at *15 (D. Me. Mar. 17, 2006). Completely exclusive methodology is not necessary. The question is whether Dr. Hefferren's study of pills is will be useful to the jury, and it is. As the Third Circuit held in In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994):

> A judge frequently should find an expert's methodology helpful even when the judge thinks that the expert's technique has flaws sufficient to render the conclusions inaccurate. He or she will often still believe that hearing the expert's testimony and assessing its flaws was an important part of assessing what conclusion was correct and may certainly still believe that a jury attempting to reach an accurate result should consider the evidence.

Id. at 744-45.

Dr. Hefferren began his study of pill shapes responding to poison control and similar queries on an *ad hoc* basis for the American Medical Association. See Hefferren Deposition, pgs. 95-96, App. 3. Prior to compiling the 5,000-drug identification guide, Dr. Hefferren published a number of smaller guides to particular drugs. See Hefferren Deposition, pg. 70. To build the identification guide, Dr. Hefferren created a taxonomy of all pills by shape, coating, marking, and other identifying factors, then measured each pill's dimensions. See id., pgs. 139-

42. The research effort attempted to include all drugs considered “major” by the American Medical Association. See id., pg. 108.

During the compilation of the identification guide, Dr. Hefferren found that the number of uncoated, white tablets on the market decreased in favor of more identifiable dosage forms. See Hefferren Deposition, pg. 110. From the application of his pill taxonomy to the DES pills with known shapes and forms, he concluded that the “majority of diethylstilbestrol are red, round, biconvex, sugar-coated tablets.” See Hefferren Deposition, pg. 162. Despite the unknown factors in DES litigation which stem from the passage of time, Dr. Hefferren’s testimony sheds light on the product identification of pills and tablets during the 1960’s and the relative difficulty of creating a pill that looked like the one at issue in this case. Dr. Hefferren is qualified to make that judgment from working in the field of pill formulation since the mid-1950’s. Defendant is free to challenge Dr. Hefferren on cross-examination as to how exhaustive his conclusion can be, or produce an identical pill as an alternative, but that does not change the fact that Dr. Hefferren has extensive experience in pill shape during the early 1960’s and his methodology is sufficiently rigorous to allow the jury to draw their own conclusions about the likelihood of a duplicate pill to Lilly’s.

Lilly’s claims that Dr. Hefferren did not sufficiently keep up with the literature to know whether or not Lilly’s 25mg uncoated DES pill are ironic, given that Lilly was Dr. Hefferren’s proponent in prior DES litigation and relied on Dr. Hefferren’s work in DES cases involving pills throughout the 60’s, see App. 2. Other courts have found that a practitioner who is semi-retired, but still consults, may be an expert despite the reduction in his contact with the current state of the art. See, e.g., NIC Holding Corp. v. Lukoil Pan-Am’s LLC, 05 Civ. 9372, 2007 U.S. Dist. LEXIS 36680 at *9 (S.D.N.Y. May 16, 2007). Expert testimony is reliable if it is "grounded in a mixture of common sense and the affiant's personal experience" in an industry. See Minott v. Smith, No. 03-10-P-H, 2003 U.S. Dist. LEXIS 15574 at *13-14 (D. Me. Sept. 5, 2003), aff'd 388 F.3d 354 (1st Cir. 2004).

IV. CONCLUSION

Dr. Hefferren's education, experience, and research in pharmaceuticals allows him to testify as to the likelihood of two pills existing with the same shape, color, and markings of Lilly's 25mg DES product. Lilly has every right to come up with a pill that matches Plaintiff's mother's description or another expert to discount Dr. Hefferren's testimony that its pill is unique; that is what trials are about.

WHEREFORE, for the foregoing reasons, Plaintiffs respectfully submit that Defendant's Motion to Exclude the Testimony of John J. Hefferren be denied.

Dated: October 5, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 5, 2007, I electronically filed Plaintiff's Opposition to Eli Lilly and Company's Motion to Exclude the Testimony of John J. Hefferren with the Clerk of Courts using the CM/ECF system. The CM/ECF system will send notification of such filing to all counsel of record.

Dated: October 5, 2007

/s/ William C. Knowles